

## REMARKS

Claim 13 is currently amended. Claims 1-23 remain before the Examiner for reconsideration.

In the Office Action dated March 14, 2006, the Examiner rejected Claims 1-23 under 35 U.S.C. 102(b) "as being anticipated by Trocki (US 6,652,489 B2)." Specifically, the Examiner asserted that:

Trocki includes a syringe for use with an injector comprising a syringe retaining mechanism including a flexible ring (**Col 15, lines 64-67**), the syringe comprising: a body comprising a rearward end and a forward end; a plunger movably disposed within the body; at least one attachment member (**Fig. 1, front removable portion**) associated with the body, the at least one attachment member cooperating with the flexible ring of the syringe retaining mechanism to releasably attach the syringe to the injector; and at least one release member associated with the body, the at least one release member operable to cause deformation of the flexible ring to enable release of the syringe from attachment with the injector upon rotation of the syringe about its axis relative to the injector, the at least one release member being positioned axially forward of the at least one attachment member. (**Col 48, lines 27-40**)

Regarding claim 2, Trocki includes the syringe wherein the at least one attachment member comprises a radially outward extending flange (**Col 15, lines 35-40**) encompassing the entire perimeter of the syringe. (**Col 48, lines 57-60**).

Regarding claim 3, Trocki discloses the syringe wherein the attachment flange has a sloped rearward surface to facilitate interaction with the flexible ring of the retaining mechanism. (**Col 15, lines 5-15**)

Regarding claim 4, Trocki discloses the syringe wherein the at least one attachment member comprises a plurality of radially outward extending flanges positioned around the perimeter of the syringe. (**Fig. 15**)

Regarding claim 5, Trocki discloses the syringe further comprising a flange member associated with the body and adapted to contact a corresponding surface of the injector when the syringe is releasably engaged therewith, the flange member being positioned axially forward of the at least one release member. (**Col 17, lines 57-65**)

Regarding claim 6, Trocki discloses the syringe wherein the flange

member is adapted to substantially prevent fluid from entering the interior of the injector. **(Col 23, lines 48-55)**

Regarding claim 7, Trocki discloses the syringe wherein contact of the flange member with the corresponding surface of the injector is an indication of proper axial positioning of the syringe with respect to the injector for releasable engagement of the syringe to the injector. **(Fig. 41B, line B)**

Regarding claim 8, Trocki discloses the syringe wherein the at least one attachment member is associated with the rear end of the body. **(Fig. 57)**

Regarding claim 9, Trocki discloses the syringe wherein the at least one release member includes a plurality of radially outward projecting members that deform the flexible ring upon rotation of the syringe about its axis to a disengagement position. **(Col 15, lines 5-10)**

Regarding claim 10, Trocki discloses the syringe wherein the at least one attachment member comprises a radially outward extending flange encompassing the entire perimeter of the syringe and the projecting members extend radially outward at least the same amount as the attachment member. **(Fig. 57 & 82)**

Regarding claim 11, Trocki discloses the syringe wherein the projecting members directly contact the flexible ring to deform the flexible ring. **(Col 15, lines 5-10, Fig. 59)**

Regarding claim 12, Trocki discloses the syringe wherein the plunger releasably engages the drive member of the injector via a flexible ring. **(Detailed descrip 12, Fig. 59)**

Regarding claim 13, Trocki discloses an injector for injecting fluid from a syringe mounted thereon, the injector comprising: a housing; a drive member at least partially disposed within the housing and operable to engage a plunger disposed within the syringe; and a syringe retaining mechanism associated with the housing and being operable to seat the syringe upon axial rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation of syringe about the axis of the syringe, the syringe retaining mechanism consisting essentially of a flexible ring maintained at a fixed axial position within the syringe retaining mechanism. **(Col 48, lines 27-40, Col 49, lines 22-25)**

Regarding claim 14, Trocki discloses an injector system for injecting fluid comprising: a syringe comprising: a body comprising a rearward end and a forward end; a plunger movably disposed within the body; at least one attachment member associated with the body, and at least one release

member associated with the body, the at least one release member being positioned axially forward of the attachment member, and an injector comprising: a housing; a drive member at least partially disposed within the housing and operable to engage the plunger disposed within the syringe; and a syringe retaining mechanism associated with the housing and being operable to seat the syringe upon axial rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation of syringe about the axis of the syringe, the syringe retaining mechanism comprising a flexible ring maintained at a fixed axial position within the syringe retaining mechanism; the flexible ring being in a first shape adapted to engage the at least one attachment member of the syringe when the syringe is seated within the syringe retaining mechanism and the syringe is positioned about its axis at an engagement position, the flexible ring being in a second shape adapted to release the syringe when the syringe is seated within the syringe retaining mechanism and the syringe is positioned about its axis at a disengagement position, wherein the at least one release member causes the flexible ring to be in the second shape. **(Col 15, lines 5-10, Claims 1 & 16)**

Regarding claim 15, Trocki discloses the injector system wherein the at least one release member comprises a plurality of radially outward projecting members that deform the flexible ring upon rotation of the syringe about its axis to the disengagement position. **(Col 49, lines 22-25).**

Regarding claim 16, Trocki discloses the injector system wherein the at least one attachment member comprises a radially outward extending flange encompassing the entire perimeter of the syringe and the projecting members extend radially outward at least the same amount as the attachment member. **(Claims 18, 21, & 29)**

Regarding claim 17, Trocki discloses the injector system wherein the projecting members directly contact the flexible ring to deform the flexible ring. **(Col 5, lines 5-25)**

Regarding claim 18, Trocki discloses an injector for injecting fluid from a syringe mounted thereon, the injector comprising: a housing; a drive member at least partially disposed within the housing, the drive member comprising a flexible ring disposed thereon operable to engage a plunger disposed within the syringe, the flexible ring being in a first state adapted to engage the plunger and form a connection therewith when the plunger is rotated about its axis to a first position, the flexible ring deforming to a second position adapted to enable release of the plunger when the plunger is rotated about its axis to a second position; and a syringe retaining mechanism associated with the housing. **(Col 5, lines 5-30, Fig. 59)**

Regarding claim 19, Trocki discloses a syringe for use with an injector comprising a syringe retaining mechanism, the syringe comprising: a body comprising a rearward end and a forward end; a plunger movably disposed within the body; and at least one attachment member associated with the body, the at least one attachment member comprising a flexible ring operable to releasably attach the syringe to the injector. **(Col 15, lines 5-10, Fig. 1, 2, 43a)**

Regarding claim 20, Trocki discloses the syringe wherein rotation of the syringe about its axis when attached to the injector causes deformation of the flexible ring to enable detachment of the syringe from the injector. **(Col 1, lines 44-50)**

Regarding claim 21, Trocki discloses an injector system for injecting fluid comprising: a syringe comprising: a body comprising a rearward end and a forward end; a plunger movably disposed within the body; and at least one attachment member associated with the body, the at least one attachment member comprising a flexible ring operable to releasably attach the syringe to the injector; and an injector comprising: a housing, a drive member at least partially disposed within the housing and operable to engage the plunger disposed within the syringe; and a syringe retaining mechanism associated with the housing and being operable to seat the syringe upon axially rearward motion of the syringe relative to the syringe retaining mechanism regardless of the orientation of syringe about the axis of the syringe, the syringe retaining mechanism defining an opening into which the syringe is insertable and comprising at least one abutment member to abut the flexible ring of the syringe and thereby resist forward axial movement of the syringe when the flexible ring is in a first shape, and at least one release member adapted to contact the flexible ring and force the flexible ring into a second shape to enable release of the syringe from attachment to the injector when the syringe is rotated about its axis to a disengagement position. **(Col 15, lines 5-30, Fig. 74-76, Claims 16 & 18)**

Regarding claim 22, Trocki discloses an injector system for injecting fluid composing: a syringe comprising: a body comprising a rearward end and a forward end; a plunger movably disposed within the body, the plunger comprising a flexible ring; at least one attachment member associated with the body; and an injector comprising: a housing; a drive member at least partially disposed within the housing and operable to engage the flexible ring of the plunger to releasably connect the plunger and the drive member; and a syringe retaining mechanism associated with the housing to form a releasable engagement with the attachment member of the syringe. **(Detailed descip 5 & 6, Fig. 1, #40)**

Regarding claim 23, Trocki discloses a syringe comprising: a body comprising a rearward end and a forward end; and a plunger movably disposed within the body, the plunger comprising a flexible ring adapted to form a releasable connection with a drive member adapted to move the plunger within the syringe. (Col 15, lines 5-20, Fig. 1, 2, 43a).

Applicants respectfully traverse the Examiner's rejection.

To assert anticipation under Section 102(b) the cases hold that the Examiner:

must show that each element of the claim in issue is found, either expressly described or under principles on inherency, in a single prior art reference, or, that the claimed invention was previously known or embodied in a single prior art device or practice.

Kalman v. Kimberly-Clark Corp., 713 F.2d 760, 771, 218 USPQ 781, 789 (Fed. Cir. 1983), cert. Denied, 465 U.S. 1026 (1984); Tyler Refrigeration v. Kysor Industrial Corp., 777 F.2d 687, 689, 227 USPQ 845, 846-47 (Fed. Cir. 1984) (judgment of anticipation reversed). "In deciding the issue of anticipation, the trier of fact must identify the elements of the claims, determine their meaning in the light of the specification and prosecution history, and identify corresponding elements disclosed in the allegedly anticipating reference." Lindemann, 730 F.2d at 1458, 221 USPQ at 485; Kalman, 713 F.2d at 771, 218 USPQ at 789.

"The test for determining if a reference anticipates a claim of a patent is whether the reference contains within its four corners adequate directions for the practice of the patent claim ... ." Kistler Instrument A.G. v. United States, 628 F.2d 1303, 1311, 203 USPQ 511, 519, aff'd., 211 USPQ 920 (Ct. Cl. 1980). The reference, whether foreign or domestic, patent or otherwise, must be construed strictly for what it "clearly and definitely discloses." Application of Boling, 292 F.2d 306, 310-11, 130 USPQ 161, 164 (CCPA 1961); Aluminum Co. of Am. v. Sperry Products, Inc., 285 F.2d 911, 922, 127 USPQ 394, 403 (6th Cir. 1960), cert. denied, 368 U.S. 890 (1961). A patent is not anticipated by a reference "unless the latter exhibits the invention in such full, clear and exact terms as to enable any person skilled in the art to practice it without making experiments." 285 F.2d at 922, 127 USPQ at 403.

Applicants respectfully assert that, under the appropriate standard as set forth above, Trocki does not anticipate the present invention. Initially, applicants address below the Examiner's rejection of each independent claim.

With respect to independent claim 1, Trocki does not disclose or suggest a syringe comprising at least one release member associated with a syringe body that is positioned axially forward of the at least one attachment member of the syringe and that is operable to cause deformation of a flexible ring of a retaining mechanism of an injector to enable release of the syringe. Trocki discloses use of a flexible ring 4068 as illustrated, for example, in Figures 56 and 57 as part of a release/connector mechanism 4010 to releasably attach syringe to injectors thereof. Contrary to the present invention, however, release/connector mechanism 4010 of Trocki includes a rotating ring 4028 disposed to the rear of flex ring 4026 (see Figures 56 and 57) to enable release of a syringe attached thereto. Because the rotating ring 4028 is positioned to the rear of flex ring 4026 of Trocki, syringe 4012 of Trocki includes tabs or projections 4050 axially rearward of attachment member or ridge 4044 to cooperate with rotating ring 4028 to release syringe 4012 from connection with release/connector mechanism 4010. For example, as set forth at Col. 33, line 64 to col. 34, line 7 of Trocki:

As shown in Figures 55-57, ridge 4044 includes two parts, a sloping section 4046 and a shoulder section 4048 that is essentially perpendicular to the exterior surface of cylindrical body 4030. At least one, and preferably two or more, extending tabs or projections 4050 are provided at rear end 4022 of syringe 4012. Tabs 4050 engage grooves 4052 provided in ring 4028. Alternatively, as would be understood by those skilled in the art, slots, recesses or divots, etc. could be provided in rear end 4022 of syringe 4012 and tabs or projections could be provided on the interior surface of rotating ring 4028.

Contrary to the Examiner assertion, Trocki does not disclose or suggest at Col. 48, lines 27-40 cited by the Examiner or anywhere else therein a syringe comprising a release member positioned axially forward of an attachment member as claimed in the present invention. Claim 1 of Trocki, at Col. 48, lines 27-41 thereof, indicates merely that the attachment member of Trocki is adapted to releasably engage the syringe retaining

mechanism of Trocki regardless of the orientation of the syringe about its axis with respect to the injector.

The present inventors have discovered that positioning a release member axially forward of the attachment member of a syringe to cooperate with a syringe attachment mechanism of an injector including a flexible ring eliminates the need for a rotating ring 4028 of Trocki and/or other release elements of an injector, thereby providing a substantial improvement and/or simplification as compared to the prior art.

Applicants respectfully assert that the above arguments are also directly applicable to and refute the Examiner's rejection of independent claim 14, which sets forth *inter alia*: an injector system comprising a syringe comprising at least one release member positioned axially forward of the at least one attachment member of the syringe. Claim 14 also sets forth that the flexible ring of the injector is in a second shape adapted to release the syringe when the syringe is seated within the syringe retaining mechanism and the syringe is positioned about its axis at a disengagement position, wherein the at least one release member causes the flexible ring to be in the second shape. Such an injector system is clearly not disclosed or suggested at col. 15, lines 5-10, claim 1 or claim 16 of Trocki, as cited by the Examiner, or elsewhere within Trocki.

With respect to independent claim 13, Trocki does not disclose or suggest a syringe retaining mechanism operable to releasably seat a syringe and consisting essentially of a flexible ring maintained at a fixed axial position within the syringe retaining mechanism. As set forth above, the release/connector mechanism 4010 of Trocki requires rotating ring 4028 to enable releasable engagement of the syringe of Trocki. Applicants have amended claim 13 to more clearly set forth that the syringe retaining mechanism of the present invention is operable to releasably seat the syringe upon axial rearward motion of the syringe. Col. 49, lines 22-25 of Trocki, cited by the Examiner, merely sets forth a preamble for a claim (claim 16) for a syringe of Trocki, which indicates that the injector in connection with which the syringe of claim 16 of Trocki is used comprises a retaining mechanism "including" a flexible ring. Col. 48, lines 27-40 cited by the Examiner has been addressed above. Trocki does not disclose or

suggest at col. 48, lines 27-40 or col. 49, lines 22-25, as cited by the Examiner, or elsewhere therein a retaining mechanism consisting essentially of a flexible ring.

With respect to independent claim 18, the Examiner cites col. 5, lines 5-30 and Figure 59 of Trocki as disclosing a drive member comprising a flexible ring. However, col. 5, lines 5-30 of Trocki merely disclose that a piston (or drive member) and a plunger can include an engagement mechanism to provide for connected interaction during an injection and/or aspiration operation. Furthermore, Figure 59 of Trocki discloses only a syringe release/connector mechanism, and does depict a drive member. Claim 18 of the present application sets forth, *inter alia*:

a drive member at least partially disposed within the housing, the drive member comprising a flexible ring disposed thereon operable to engage a plunger disposed within the syringe, the flexible ring being in a first state adapted to engage the plunger and form a connection therewith when the plunger is rotated about its axis to a first position, the flexible ring deforming to a second position adapted to enable release of the plunger when the plunger is rotated about its axis to a second position

Trocki (in the portions thereof cited by the Examiner or elsewhere) does not disclose a drive member comprising a flexible ring disposed thereon, wherein the flexible ring is deformable when the plunger is rotated from a first position to a second position.

With respect to independent claims 19 and 21, Trocki does not disclose or suggest a syringe comprising an attachment member associated with the syringe body and comprising a flexible ring operable to releasably attach the syringe to the injector. Contrary to the Examiner's assertion, there are no flexible rings on any attachment member of the syringes of Trocki. The Examiner refers to col. 15, lines 15-30 of Trocki, to support the incorrect assertion that Trocki discloses a syringe comprising an attachment member comprising flexible ring. However, that section of Trocki discloses volumetric gradations and indicating mechanisms for readily detecting whether a syringe contains liquid or air. Similarly, the Examiner's reference to Figs. 1, 2, 43a, and 74-76, are also puzzling. As discussed above, Trocki discloses an injector including release/connector mechanism 4010 to releasably attach a syringe wherein the injector



includes a flex ring 4026. However, Trocki does not disclose or suggest in col. 15, lines 15-30 or in Figs. 1, 2, 43a, and 74-76, cited by the Examiner, or elsewhere, a syringe comprising an attachment member comprising a flexible ring.

With respect to independent claims 22 and 23, Trocki does not disclose or suggest a plunger movably disposed within a syringe body and comprising a flexible ring. Further, Trocki does not disclose or suggest an injector comprising a drive member at least partially disposed within the housing and operable to engage the flexible ring of the plunger to releasably connect the plunger and the drive member. The Examiner inexplicably refers to the detailed description 5, 6, col. 15, lines 5-20 and Figs. 1, 2, and 43a of Trocki in erroneously asserting that Trocki discloses a plunger comprising a flexible ring adapted to form a releasable connection with a drive member. None of these sections of Trocki or any other section of Trocki discloses or suggests a plunger comprising a flexible ring adapted to form a releasable connection with a drive member.

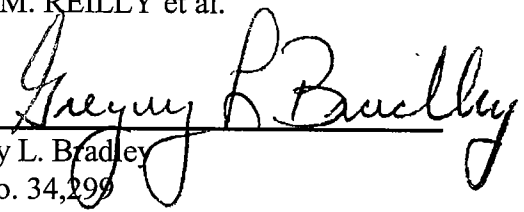
For the reasons set forth above, the applicants respectfully assert that the present invention as claimed is patentably distinct over Trocki. Applicants respectfully assert that the Examiner has impermissibly ignored express claim limitations in rejecting each of independent claims 1, 13, 14, 18, 19, and 21-23 of the present application over Trocki. See Ex Parte Murphy and Burford, 217 USPQ 479, 481 (P.O. Bd. Appls. 1982) (“it is error to ignore specific limitations distinguishing over the cited reference”); In re Boe, 505 F.2d 1297, 184 USPQ 38 (CCPA). Given the clear distinctions between the disclosure of Trocki and the invention set forth in independent claims 1, 13, 14, 18, 19, and 21-23 of the present invention, applicants have not specifically addressed herein any deficiencies in the Examiner’s assertions with respect to dependent claims 2-12, 15-17, and 20. Applicants respectfully reserve the right to address such assertions.

In view of the above amendments and remarks, applicants respectfully requests that the Examiner, indicate the allowability of the claims and arrange for an official Notice of Allowance to be issued in due course.

Respectfully submitted,

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